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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,274	07/24/2003	Loksidh D. Ganorkar	00787/3/US	9609

7590 09/15/2006

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EXAMINER
ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,274	GANORKAR ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/17/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating specific diseases (e.g., Parkinson's and sexual dysfunction), which can be treated by a dopamine D_2 receptor agonist, does not reasonably provide enablement for "treating a subject having a condition or disorder for which a dopamine agonists is indicated" as broadly claimed in claim 21. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth hereinbelow.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The claimed invention relates to treating a subject having a condition or disorder for which a dopamine agonists is indicated, which encompasses both any animal and any disease that would require a dopamine agonists. Various diseases having various different causes are not treatable by a single composition. Given the great diversity between various diseases that would require a dopamine agonist (psychosis, schizophrenia, depression, restless leg syndrome, neurological diseases, etc.), the unpredictability of treating an animal (e.g., no specific disease) has a number of facets, as discussed hereinafter. This claim is a reach through claim, as various conditions or disorders for which a dopamine agonist is indicated may not have been discovered yet.

Treatment of Disease Type

While the state of the art is relatively high with regard to the treatment of specific diseases with a specific agent, it is long underdeveloped with regard to the treatment of an animal broadly, that is, general treatment, with no specific disease combined with a specific drug therefore. In particular, there is no known "treatment" drug, that can treat, "all that ails you". This is why the National Cancer Institute (NCI) has the extensive *in vitro* drug-screening program it does. As discussed by the court in In re Brana, 51 F.3d 1560 (Fed. Cir. 1995), *in vitro* assays are used by NCI (such as the P388 and L1210

lymphocytic leukemia tests at issue therein) to measure the potential antitumor properties of a candidate compound. Brana at 1562-63. If success is shown in this initial screening step, this demonstrates that at least one cancer type (e.g., lymphocytic leukemia) is sensitive thereto, and provides the incentive to select it for further studies to determine its usefulness as a chemotherapeutic agent against other cancer types (lung, breast, colon, etc.) *Id.* at 1567-68. These *in vitro* tests are considered reasonably correlative of success *in vivo*.

Thus, a considerable amount of *in vitro* empirical testing is required, with no *a priori* expectation of success being present, before a candidate for even treating a specific disease, such as, cancer.

2. The breadth of the claims

The claims are very broad and inclusive of "treatment of a subject" generally, which includes any treatment. Clearly, the methods are only used to treat diseases, in which, providing a pharmaceutical compound of claim 1, offers some treatment for Parkinson's or sexual dysfunction.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction for ascertaining, *a priori*, which diseases can be treated, except sexual dysfunction and Parkinson's.

4. The quantity of experimentation necessary

The lack of adequate guidance from the specification or prior art with regard to the actual treatment fails to rebut the presumption of unpredictability present in this art.

Applicants fail to provide the guidance and information required to ascertain which particular disease the claimed agent will be effective against without resorting to undue experimentation. Applicant's limited disclosure of the treatment of is not sufficient to justify claiming all treatment broadly.

In order to expedite the examining process the examiner will simply search for a treatment for Parkinson's or sexual dysfunction by orally administrating to the subject the pharmaceutical composition of claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3,20 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically all the claims recite starch as having a specific tensile strength as a solid fraction representative of the tablet, but since the tablet comprises other ingredients such as the active and HPMC the tensile strength is not a true measurement of the starch's tensile strength but the overall tablets tensile strength. To expedite the examining process the examiner will search for a tablet with the disclosed ingredients and tensile strength.

Claim 20 contains the trademark/trade name HPMC type 2208. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of **35 U.S.C. 112**, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used

properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a specific HPMC and, accordingly, the identification/description is indefinite. To expedite the examining process the examiner will simply search for HPMC and ignore the limitation of type 2208.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17,20-21,23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ju (US 6,197,339 B1, cited by applicants).

Ju teaches a sustained release tablet to treat Parkinson's disease, the tablet comprises 1-56 mg of sumanirole maleate, 60-69% pregelatinized starch and 30-40% HPMC. See col 2 lin1-60, examples and claims. Regarding the limitations on the tensile strength of starch, the only limitation used in the body of the claims on the type of starch that would meet the limitation of the tensile strength is a pregelatinized starch, therefore Ju meets this limitation because the same compound will have the same properties such as tensile strength when compressed under the same amount of force to form a tablet.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ju (US 6,197,339 B1, cited by applicants)

Ju is disclosed above. Ju does not disclose a salt of (R)-5,6-dihydro-5-(methylamino)-4H-imidazo[4,5-ij]-quinoline-2(-1H)-thione for use in the composition but it is the opinion of the examiner that this is a very obvious variant or homolog of sumanirole maleate different from each other only by the substitution of a carbonyl C=O with a thionyl C=S, therefore the limitations in claim 18 and 19 are met. Regarding claim 22, while Ju does not specifically recite once a day administration it would have been obvious that the exact dosage and frequency of administration depends on the severity of the condition being treated, the weight, general physical condition of the patient, other medications being taken by the patient. See col 3 lin 45-54. Regarding claim 24, while Ju is silent on the particular treatment of sexual dysfunction with the

composition disclosed it is obvious that the same chemical compound will have the same activity in a human body and have the same effects, therefore the limitation is met.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ju (US 6,197,339 B1, cited by applicants) in view of Moon et al. (US 5,273,975, cited by applicants) in view of Michaud et al. (EP 0,933,079 A1, cited by applicants).

Ju is disclosed above. Ju does not disclose a salt of (R)-5,6-dihydro-5-(methylamino)-4H-imidazo[4,5-ij]-quinoline-2(-1H)-thione for use in the composition, a daily administration of the composition, the tensile strength of the tablet composition nor the treatment of sexual dysfunction.

Moon discloses all of the compounds encompassed by applicant including sumanirole maleate and (R)-5,6-dihydro-5-(methylamino)-4H-imidazo[4,5-ij]-quinoline-2(-1H)-thione maleate, the compounds can be administered once daily as tablets for the treatment of Parkinson's and to stimulate sexual activity. See abstract, col 1 lin 53-col 2 lin 23,col 9 lin 58-col 10 lin 14 and claims. From the disclosure of Moon it is obvious that the compounds claimed by applicant are obvious homologs of each other and would therefore by interchangeable including (R)-5,6-dihydro-5-(methylamino)-4H-imidazo[4,5-ij]-quinoline-2(-1H)-thione maleate and sumanirole maleate different from each other only by the substitution of a carbonyl group C=O with a thionyl group C=S.

Michaud is used only to show that pregelatinized starch was already known to have tensile strength within applicants claimed amounts when compressed into a tablet form. See tables 3,6,9-13.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Ju discloses all of applicants claimed invention except for the exact compound (R)-5,6-dihydro-5-(methylamino)-4H-imidazo[4,5-ij]-quinoline-2(-1H)-thione maleate, administrating the tablet once daily, the treatment of sexual dysfunction and the tensile strength of the tablet. Moon and Michaud showed that the use of the composition disclosed in Ju could be used to treat sexual dysfunction and administered once a day, the exact compound claimed in claim 19 and the tensile strength of pregelatinized starch were all well known at the time of the invention. The motivation to combine the above documents a treatment for Parkinson's disease or sexual dysfunction comprised of administering a tablet with the following active ingredients sumanirole maleate or (R)-5,6-dihydro-5-(methylamino)-4H-imidazo[4,5-ij]-quinoline-2(-1H)-thione maleate and the following inactive ingredients pregelatinized starch and HPMC. The advantage of such a composition would be a tablet having a sufficient hardness to resist erosion and the tabulating process. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER